

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

SUSAN BREEN,
Plaintiff
v.
ETHICON, INC., JOHNSON &
JOHNSON,
Defendant

CASE NO. C20-5595 BHS

ORDER GRANTING
DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT

**ETHICON, INC., JOHNSON &
JOHNSON,**

Defendants.

This matter comes before the Court on Defendants Ethicon, Inc. and Johnson & Johnson's (collectively "Defendants") motion for summary judgment. Dkts. 22, 66. The Court has considered the pleadings filed in support of and in opposition to the motion and the remainder of the file and hereby grants the motion for the reasons stated herein.

I. PROCEDURAL HISTORY

On August 31, 2018, Plaintiff Susan Breen filed suit against Defendants in the MDL *In re Ethicon, Inc. Products Liability Litigation*, MDL No. 2327, located in the Southern District of West Virginia. Dkt. 1. On December 19, 2019 Defendants moved for summary judgment. Dkts. 22, 23. On January 3, 2020, Breen responded. Dkt. 26. On January 10, 2020, Defendants replied. Dkt. 28. The Southern District of West Virginia

1 did not resolve the motion prior to transfer. On June 22, 2020, the case was transferred to
2 this Court. Dkt. 43. The Court renoted Defendants' fully briefed summary judgment
3 motion and allowed Defendants to file a renewed motion in light of new testimony from
4 Breen's case-specific expert. Dkt. 64.

5 On November 16, 2020, Defendants filed a renewed motion for summary
6 judgment. Dkt. 66. On December 8, 2020, Breen responded. Dkt. 69. On December 18,
7 2020, Defendants replied. Dkt. 73.

8 **II. FACTUAL BACKGROUND**

9 Breen brings claims against Defendants arising out of her surgical implantation of
10 TVT-Exact—a prolene mesh implant—to treat her stress urinary incontinence (“SUI”).
11 Dkt. 1; Dkt 67-1, Plaintiff Fact Sheet (“PFS”), at 6. Dr. Marc Mitchell performed surgery
12 on Breen to implant the TVT-Exact device on September 14, 2010 in Silverdale,
13 Washington. PFS at 6. Breen alleges that she sustained the following injuries because of
14 her 2010 implant surgery: “Exposed mesh; doctor saw the mesh sticking out, recurrence
15 of incontinence, [and] cystitis cystica[.]” *Id.* at 7.

16 Dr. Mitchell testified that, prior to the 2010 surgery, he did not rely on Ethicon to
17 instruct him on how to implant the TVT-Exact and that he relied on his training and
18 education to inform him as to the risks and potential complications of the TVT-Exact.
19 Dkt. 70-4, Deposition of Dr. Marc Mitchell (“Mitchell Depo.”), at 15:18–21, 19:21–
20 20:15. Dr. Mitchell further testified that he has never relied on written materials from
21 Ethicon as a source of knowledge about the risks of the implant and that he was aware
22 that, in 2008, the FDA had issued a public health notification regarding the use of

1 transvaginal mesh for the treatment of stress incontinence. *Id.* at 20:17–21:6. Dr. Mitchell
2 concluded that he was aware of the “risks, complications, and subsequent issues” of the
3 TVT-Exact in 2010 and that he would still recommend the TVT-Exact to treat women’s
4 SUI today. *Id.* at 21:21–22:1, 81:13–20, 129:20–130:2.

5 Four years later, on October 20, 2014, Breen elected to undergo a surgical revision
6 of her TVT-Exact to remove the implant because of exposed mesh. PFS at 7; Dkt. 67-3.
7 Breen first experienced exposed mesh in approximately September 2014. PFS at 7–8. She
8 alleges that she was told by Dr. Mitchell that her body was extruding the implant, but he
9 did not tell her why. Dkt. 69 at 2. She states that she believed her body was pushing the
10 implant out and that she did not believe anything was wrong with the implant that was
11 causing the extrusion. *Id.* Breen testified at her deposition that she experienced
12 incontinence the next day after the 2014 surgery and that the incontinence was the same
13 as it was prior to the original surgery in September 2010. Dkt. 67-5, Deposition of Susan
14 Breen (“Breen Depo.”), at 25:16–26:1. She further testified that she spoke with Dr.
15 Mitchell after the 2014 surgery about the return of her incontinence and that Dr. Mitchell
16 told her he could not help her anymore because of her physical condition. *Id.* at 29:15–24.
17 Dr. Mitchell did not recommend that Breen see a urologist at that time. *Id.* at 30:6–7.

18 Breen first attributed her bodily injuries to the TVT-Exact implant when she saw
19 an advertisement about medical mesh implant claims. *Id.* at 51:9–18; PFS at 8. She does
20 not remember exactly when she saw the advertisement, but she testified that she was not
21 seeing Dr. Mitchell at that time. Breen Depo. at 51:19–23. Breen’s last appointment with
22 Dr. Mitchell was on February 5, 2015. Mitchell Depo. at 72:5–7. Breen first contacted an

1 attorney regarding her potential case on September 3, 2015. Dkt. 70-13. She additionally
 2 testified at her deposition that she was not shown any brochures or pamphlets in
 3 connection to her implant, Breen Depo. at 71:12–15, and that she has never—either
 4 before surgery or before her deposition—researched mesh implants online, *id.* at 51:4–8.

5 Breen has thus brought product liability and fraud claims against Defendants for
 6 her injuries arising from the surgical implantation of the TVT-Exact.

7 III. DISCUSSION

8 Defendants move for summary judgment on all of Breen’s claims,¹ arguing that
 9 her product liability claims are time-barred. In the alternative, Defendants argue that the
 10 Court should dismiss her product liability claims and fraud-based claims because there is
 11 insufficient evidence to establish causation.

12 A. Summary Judgment Standard

13 Summary judgment is proper only if the pleadings, the discovery and disclosure
 14 materials on file, and any affidavits show that there is no genuine issue as to any material
 15 fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a).
 16 The moving party is entitled to judgment as a matter of law when the nonmoving party

17
 18 ¹ Breen concedes to the dismissal of the following claims: Negligence (Count I), Strict
 19 Liability – Manufacturing Defect (Count II), Strict Liability – Defective Product (Count IV),
 20 Negligent Infliction of Emotional Distress (Count X), Breach of Express Warranty (Count XI),
 21 Breach of Implied Warranty (Count XII), Violation of Consumer Protection Laws (Count XIII),
 22 Gross Negligence (Count XIV), and Unjust Enrichment (Count XV). Summary judgment is
 granted on the conceded claims. Breen’s remaining claims are: Strict Liability – Failure to Warn
 (Count III), Strict Liability – Design Defect (Count V), Common Law Fraud (Count VI),
 Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent
 Misrepresentation (Count IX), Punitive Damages (Count XVII), and Discovery Rule and Tolling
 (Count XVIII).

1 fails to make a sufficient showing on an essential element of a claim in the case on which
2 the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323
3 (1986). There is no genuine issue of fact for trial where the record, taken as a whole,
4 could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec.*
5 *Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (nonmoving party must
6 present specific, significant probative evidence, not simply “some metaphysical doubt”).
7 Conversely, a genuine dispute over a material fact exists if there is sufficient evidence
8 supporting the claimed factual dispute, requiring a judge or jury to resolve the differing
9 versions of the truth. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986); *T.W.*
10 *Elec. Serv., Inc. v. Pac. Elec. Contractors Ass’n*, 809 F.2d 626, 630 (9th Cir. 1987).

11 The determination of the existence of a material fact is often a close question. The
12 Court must consider the substantive evidentiary burden that the nonmoving party must
13 meet at trial—e.g., a preponderance of the evidence in most civil cases. *Anderson*, 477
14 U.S. at 254; *T.W. Elec. Serv., Inc.*, 809 F.2d at 630. The Court must resolve any factual
15 issues of controversy in favor of the nonmoving party only when the facts specifically
16 attested by that party contradict facts specifically attested by the moving party. The
17 nonmoving party may not merely state that it will discredit the moving party’s evidence
18 at trial, in the hopes that evidence can be developed at trial to support the claim. *T.W.*
19 *Elec. Serv., Inc.*, 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory,
20 nonspecific statements in affidavits are not sufficient, and missing facts will not be
21 presumed. *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 888–89 (1990).

22

1 **B. Product Liability Claims**

2 **1. Statute of Limitations**

3 Defendants argue that Breen’s product liability claims are time-barred, while
 4 Breen argues that her claims were timely brought because they did not accrue until after
 5 2015. The Washington Products Liability Act (“WPLA”) governs all claims for product-
 6 related harm in Washington. RCW 7.72.010(4). Under the WPLA, a claim must be
 7 brought within “three years from the time the claimant discovered or in the exercise of
 8 due diligence should have discovered the harm and its cause.” RCW 7.72.060(3).

9 A statute of limitations begins to run when the underlying claim accrues—that is
 10 when a party has discovered or should have discovered the facts to support a cause of
 11 action. *Green v. A.P.C.*, 136 Wn.2d 87, 95 (1998). Washington requires “that when a
 12 plaintiff is placed on notice by some appreciable harm occasioned by another’s wrongful
 13 conduct, the plaintiff must make further diligent inquiry to ascertain the scope of the
 14 actual harm.” *Id.* at 96. To that end, Washington courts have held that “one who has
 15 notice of facts sufficient to put him upon inquiry is deemed to have notice of all acts
 16 which reasonable inquiry would disclose.” *Id.* (quoting *Hawkes v. Hoffman*, 56 Wash.
 17 120, 126 (1909)). But the question of when a plaintiff should have discovered the facts to
 18 support a cause of action so as to trigger the statute of limitations is ordinarily a question
 19 of fact. *Id.* at 100; *see also Adcox v. Children’s Orthopedic Hosp. & Med. Ctr.*, 123
 20 Wn.2d 15, 34–35 (1993); *Honcoop v. State*, 111 Wn.2d 182, 194 (1988). The defendant
 21 bears the initial burden of showing the absence of an issue of material fact. *Green*, 136
 22 Wn.2d at 100; *Young v. Key Pharms. Inc.*, 112 Wn.2d 216, 225 (1989).

1 Defendants argue that Breen had notice of sufficient facts to put her on inquiry
 2 notice because she began to experience symptoms that she attributes to the TVT-Exact
 3 approximately a month before her October 2014 revision procedure. Under this logic,
 4 Breen's WPLA claims accrued more than three years before she brought suit. But the
 5 Court has previously declined to find that plaintiffs who received an Ethicon mesh
 6 implant were on inquiry notice about the implant "when there is lacking evidence about
 7 what she would have discovered upon inquiry." *March v. Ethicon, Inc.*, No. C20-5032
 8 BHS, 2020 WL 6132212, at *4 (W.D. Wash. Oct. 19, 2020); *see also Morrow v. Ethicon,*
 9 *Inc.*, No. C20-5062 BHS, 2020 WL 6685055, at *3 (W.D. Wash. Nov. 12, 2020).

10 Defendants distinguish this case from the Court's precedent by providing a Health
 11 Notification issued by the FDA in October 2008. Dkt. 67-7. In 2008—two years before
 12 Breen's initial surgery and six years before she began experiencing symptoms—the FDA
 13 issued a notice warning healthcare practitioners of complications associated with surgical
 14 mesh to treat SUI. Furthermore, Defendants assert that "by 2012, thousands of plaintiffs
 15 had begun filing lawsuits against pelvic mesh manufacturers, including against
 16 Defendants, alleging the same types of injuries Plaintiff suffered, and caused by the same
 17 defects that Plaintiff asserts here." *Tily v. Ethicon*, No. 20-2582, 2020 WL 5369724, at *5
 18 (E.D. Pa. Sept. 8, 2020). Defendants thus argue that Breen could have discovered that
 19 other patients had experienced similar injuries from their mesh implants to treat SUI and
 20 that Breen was under inquiry notice.

21 Breen argues that the discovery rule as discussed in *North Coast Air Services, Ltd.*
 22 *v. Grumman Corp.*, 111 Wn.2d 315 (1988), is applicable to this case, and under the

1 principles of *North Coast Air* her claims are not time barred. Dkt. 69 at 10–11. In *North*
2 *Coast Air*, a pilot died in a plane crash, and the initial investigation attributed the cause to
3 the pilot’s error and concluded that the plane had no mechanical defects. 111 Wn.2d at
4 317. The plaintiff—the pilot’s father—learned eleven years later that the crash was a
5 result of a defect in the plane only after hearing reports of similar crashes. *Id.* at 317–18.
6 The plaintiff subsequently asserted products liability claims, and the defendant moved to
7 dismiss, arguing that the claims were time barred. *Id.* at 318–19.

8 The Washington Supreme Court therefore addressed whether the statute of
9 limitations for a products liability case begins to run when the harm is or should have
10 been discovered or whether “is it a question for the trier of fact to determine when ‘in the
11 exercise of due diligence’ the product’s relationship to the injury should have been
12 discovered, with the statute of limitations running from that date.” 111 Wn.2d at 317. The
13 court rejected the defendant’s argument that a claim accrues when the claimant knew or
14 should have known the immediately apparent basis for the harm, *id.* at 322–23, and rather
15 held that the statute of limitations begins to run when the claimant discovered, or should
16 have discovered, the factual causal relationship between the alleged defective product and
17 harm, *id.* at 319. Importantly, the Washington Supreme Court held that whether the
18 plaintiff in the case knew or should have known about the cause of harm was an
19 unresolved question of fact. *Id.* at 318.

20 Breen concedes that she knew of some injury because she experienced symptoms
21 following the implant of the TVT-Exact, but argues she did not suspect that the product
22

1 was defective until she saw an advertisement.² She argues that she was never told by Dr.
 2 Mitchell or any other health care provider that the TVT-Exact was defective and caused
 3 her injuries. Breen asserts that “questions of fact remain as to the extent of her suspicion
 4 and whether she would have discovered the underlying cause of her harm upon inquiry.”
 5 Dkt. 69 at 10–11. Defendants respond and argue that “reasonable minds could only
 6 conclude that due diligence would have alerted [Breen] to the factual basis for her action”
 7 more than three years before she filed suit in August 2018. Dkt. 73 at 6 (quoting *Allen v.*
 8 *State*, 118 Wn.2d 753, 760 (1992) (internal quotation marks omitted)).

9 Yet, the Washington Supreme Court held in *North Coast Air* that whether the
 10 plaintiff knew or should have known about the cause of harm was a question of fact. 111
 11 Wn.2d at 328. Even if Breen experienced injuries just before the October 2014 revision
 12 surgery, questions of fact remain as to the extent of her suspicion and whether she would
 13 have discovered the underlying cause of her harm upon inquiry. The Court agrees with
 14 Breen that questions of fact exist here as to whether she should have discovered the TVT-
 15 Exact deficiencies prior to 2015. The Court therefore declines to hold as a matter of law
 16 that Breen should have been diligent and discovered the cause of her harm. It remains a
 17
 18

19 ² Breen also argues that she first contacted counsel regarding her case on September 3,
 20 2015, however the Washington Supreme Court has rejected “a rule that would in effect toll the
 21 statute of limitations until a party walks into a lawyer’s office and is specifically advised that he
 22 or she has a legal cause of action[.]” *Reichelt v. Johns-Manville Corp.*, 107 Wn.2d 761, 772–73
 (1987). When Breen first met with her counsel is therefore irrelevant as to whether her WPLA
 claims are timely, and the Court’s analysis will focus on whether Breen had facts giving rise to a
 duty to inquire. See, e.g., *Clare v. Saberhagen Holdings, Inc.*, 129 Wn. App. 599, 604–05 (2005).

1 question of fact when Breen's WPLA claims accrued and thus whether the limitations
 2 period for them has expired.³

3 **2. Merits**

4 In the alternative, Defendants argue that Breen cannot meet the requirements of
 5 her theories of recovery under the WPLA because she cannot establish causation. Breen's
 6 remaining product liability claims are Strict Liability – Failure to Warn (Count III) and
 7 Strict Liability – Design Defect (Count V), which will be addressed in turn.

8 **a. Strict Liability – Failure to Warn**

9 The WPLA permits recovery "if the claimant's harm was proximately caused by
 10 the negligence of the manufacturer in that the product was . . . not reasonably safe
 11 because adequate warnings or instructions were not provided." RCW 7.72.030(1). To
 12 prevail on a failure to warn claim, a plaintiff must show that (1) the defendant failed to
 13 sufficiently warn, (2) the plaintiff suffered damages, and (3) the defendant's failure to
 14 sufficiently warn of the dangers was a proximate cause of the plaintiff's damages. *See,*
 15 *e.g., Little v PPG Industries, Inc.*, 19 Wn. App. 812, 818 n.3 (1978) (approving the
 16 Restatement of Torts' recitation of the elements). However, in the context of medical
 17 failure to warn claims, the duty of the manufacturer to warn is satisfied if the
 18 manufacturer gives adequate warning to the physician who prescribes or implants the
 19 product. *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13 (1978).

20

21 ³ Breen also asserts fraudulent concealment tolls the statute of limitations for her WPLA
 22 claims, *see* Dkt. 69 at 11–12, but because there are questions of fact as to whether the statute of
 limitations has run, the Court declines to address this alternative argument.

1 Defendants argue that Breen's failure to warn claim fails because Breen's
2 implanting physician—Dr. Mitchell—was aware of the specific risks and injuries Breen
3 attributes to her mesh implant and because he did not rely on any materials provided by
4 Defendants. In order to prove causation, Breen must show that her implanting physician
5 was aware of the alleged inadequate warning made by Defendants. *See Cutter v. Ethicon,*
6 *Inc.*, No. 5:19-443-DCR, 2020 WL 109809, at *8 (E.D. Ky. Jan. 9. 2020) (“Dr. Guiler
7 testified that he did not consult these materials to obtain information about the risks of
8 implanting the Prolift device in Jenesta and, in fact, has never relied on them for such
9 information.”). She must also show that her physician would have acted differently had
10 he been given an adequate warning. *See Contreras v. Bos. Sci. Corp.*, No. 2:12-cv-03745,
11 2016 WL 1436682, at *4 (S.D.W. Va. Apr. 11, 2016) (“Here, the plaintiffs have not
12 provided any citations to the record showing that Dr. Baker, the implanting physician,
13 would have taken a different course of action even if she had been given an adequate
14 warning.”); *Fulgenzi v. PLIVA*, 140 F. Supp. 3d 637, 648 (N.D. Ohio 2015) (“The
15 undisputed facts in the record establish that plaintiff’s physicians did not ever read, let
16 alone rely on, PLIVA’s inadequate 2004 warning.”); *Higgins v. Ethicon, Inc.*, No. 2:12-
17 cv-01365, 2017 WL 2813144, at *3 (S.D.W. Va. Mar. 30, 2017) (granting summary
18 judgment on a Texas law failure to warn claim because “[t]he plaintiffs have failed to
19 present any testimonial or other evidence that Dr. Anhalt would not have used or
20 prescribed the TVT-S to treat Ms. Higgins had he received a different warning.”).

21 Breen argues that Defendants failed to provide adequate warnings of the risks
22 associated with the TVT device to Dr. Mitchell. However, Dr. Mitchell testified that he

1 relied on his own knowledge to inform him as to the risks and potential complications of
2 the TVT-Exact. Washington state case law makes clear that any failure to warn by a
3 medical device or drug manufacturer is not the proximate cause of harm if the physician
4 relies on their own knowledge and does not rely on the manufacturer's labeling. *See, e.g.*,
5 *Douglas v. Bussabarger*, 73 Wn.2d 476, 478 (1968) ("However, even if we assume such
6 labeling should have taken place, defendant-Dr. Bussabarger testified that he relied on his
7 own knowledge of anesthetics and, in fact, did not read the labeling which was on the
8 container. Thus, if defendant-drug company was negligent in not labeling its container so
9 as to warn of dangers, this negligence was not a proximate cause of plaintiff's
10 disability."); *Sherman v. Pfizer, Inc.*, 8 Wn. App. 2d 686, 699 (2019) ("Defendants'
11 alleged failure to update the package inserts cannot be the proximate cause of Sherman's
12 condition as a matter of law because even if they had updated the package inserts, Dr.
13 Silverman would not have read them.").

14 Breen argues that, despite Dr. Mitchell's testimony otherwise, "there is a genuine
15 issue of material fact as to whether [Dr. Mitchell], through his own independent research,
16 is reviewing inadequate information and/or warnings that is also contained in the IFU . . .
17 and is relying on it when he's convincing his patients to consent to the implant of an
18 Ethicon TVT device." Dkt. 69 at 15–16. However, this assertion is not specific,
19 significant probative evidence to create a genuine dispute of material fact. *Matsushita*,
20 475 U.S. at 586. The uncontested, non-speculative evidence is that Dr. Mitchell did
21 not consult the IFU in decision whether to recommend the TVT-Exact to Breen prior to
22 her implant surgery. Mitchell Depo. at 15:18–21, 19:21–20:15. Even assuming that

1 Defendants' warnings were inadequate, Breen cannot establish proximate cause because
 2 Dr. Mitchell did not rely on any of Defendants' representations. Summary Judgment is
 3 therefore granted as to Breen's Strict Liability – Failure to Warn claim.

4 **b. Strict Liability – Design Defect**

5 The WPLA also allows for recovery "if the claimant's harm was proximately
 6 caused by the negligence of the manufacturer in that the product was not reasonably safe
 7 as designed[.]" RCW 7.72.030(1). To prevail in a WPLA claim for design defect, a
 8 plaintiff must show that (1) a manufacturer's product (2) not reasonably safe as designed
 9 (3) caused harm to the plaintiff. *Pagnotta v. Beall Trailers of Oregon, Inc.*, 99 Wn. App.
 10 28, 36 (2000). Here, Defendants again argue that Breen has failed to establish causation.

11 Expert testimony is not always required to establish causation for a design defect
 12 claim, but "[e]xpert testimony is required to establish causation when an injury involves
 13 obscure medical factors that would require an ordinary lay person to speculate or
 14 conjecture in making a finding." *Bruns v. PACCAR, Inc.*, 77 Wn. App. 201, 214 (1995)
 15 (internal citations omitted). Such is the case here. Breen's "required expert testimony
 16 must provide proof that the defect 'more probably than not' caused [her] injuries." *Id.* at
 17 215.

18 Breen has two experts to support her case: Dr. W. Scott Webster, her case-specific
 19 expert, and Dr. Jerry G. Blaivas, her general expert. In his disclosed expert report, Dr.
 20 Webster opines "that the cause of [Breen's] recurrent stress urinary incontinence, urinary
 21 urgency and mesh exposure are related to the Ethicon Gynecare TVT Exact implant."
 22 Dkt. 67-12 at 4. Dr. Webster additionally testified in a January 22, 2020 deposition, and

1 Defendants object to the Court's consideration of this testimony pursuant to Fed. R. Civ.
 2 P. 37(c)(1).⁴ See Dkt. 66 at 20 & n.8. Dr. Webster testified that it was his opinion that
 3 Breen's injuries were caused by the fact that "the synthetic mesh itself [i.e., the TVT-
 4 Exact] is a permanent implant, and it tends to cause a foreign body reaction." Dkt. 67-13,
 5 Deposition of Dr. W. Scott Webster, at 79:23–80:7. Dr. Webster further clarified, though,
 6 that he will only testify at trial as to what complications Breen had as a result of her
 7 implant. *Id.* at 93:18–23, 100:8–14.

8 Breen also offers the opinion of Dr. Blaivas regarding the design of the TVT-
 9 Exact; Dr. Blaivas's expert report focuses on the safety and design of the TVT-Exact. See
 10 Dkt. 70-9. He opines, for example that the "TVT Exact should not have been designed for
 11 placement in a surgically contaminated field without proper animal and clinical studies to
 12 document safety and without a clear warning about the possibility of short and long term
 13 complications." *Id.* at 5 (citations omitted). Dr. Blaivas does not offer any opinions as to
 14 whether the alleged design defects of the TVT-Exact specifically caused Breen harm.

15 Breen argues that Dr. Blaivas's opinions and Dr. Webster's opinions, when taken
 16 together, are evidence that her injuries were caused by the TVT-Exact implant and defeat
 17 summary judgment. However, the Court agrees with Defendants that the experts'

19 ⁴ Defendants assert that Dr. Webster's January 22 deposition includes testimonial
 20 opinions which were not disclosed in his Rule 26 report and that therefore his new opinions
 21 should be excluded. Breen has not responded to this argument and does not justify the failure to
 22 disclose this information. The Court will therefore only consider Dr. Webster's new testimony if
 such consideration is harmless. Fed. R. Civ. P. 37(c)(1) ("the party is not allowed to use that
 information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the
 failure was substantially justified or is harmless.").

1 opinions do not offer evidence of causation. Dr. Blaivas offers an opinion generally about
2 the safety of TVT-Exact implants. And Dr. Webster, even considering his deposition
3 testimony, offers his opinion only as to Breen's complications after her implant
4 surgery—not the cause of the complications.

5 Breen's evidence as to causation for her design defect claim is similar to the
6 evidence considered in *Abt v. Ethicon, Inc.*, No. 1:20-cv-0047 SRC, 2020 WL 4887022,
7 at *3–4 (E.D. Mo. Aug. 20, 2020). In *Abt*, the plaintiff's case-specific expert opined that
8 the defective mesh was the cause of the plaintiff's symptoms and complications, but he
9 did not connect a specific design defect with her injuries. *Id.* at *3. Like Breen, the
10 plaintiff in *Abt* also relied on her general expert, who discussed the various design defects
11 of the mesh implant generally, to establish causation. *Id.* The district court concluded
12 that, even considering the two expert reports together, “at most Abt has established
13 correlation between the implant’s design defects and her injuries; she has not shown
14 causation. Without some evidence showing her implant caused her injuries, beyond
15 conclusory statements, Abt’s claim for strict liability design defect fails.” *Id.* at *4.

16 Neither Dr. Webster nor Dr. Blaivas have opined as to whether the defects
17 identified by Dr. Blaivas caused Breen’s injuries. This evidence does not establish that
18 “the defect ‘more probably than not’ caused [Breen’s] injuries.” *Bruns*, 77 Wn. App. at
19 215. As such, Breen has not created a genuine issue of material fact as to causation. The
20 Eastern District of Washington has also reached this conclusion. *See Lynch v. Ethicon,*
21 *Inc.*, 2020 WL 5733184, at *2 (E.D. Wash. Sept. 24, 2020.) (“But without an expert
22 opinion asserting a causal link between the general *design defects* identified by Dr.

1 Veronikis and Lynch's injuries, Lynch has not established a genuine issue of material
 2 fact." (emphasis in original)). Summary judgment is therefore granted as to her Strict
 3 Liability – Design Defect claim.

4 **C. Fraud-Based Claims**

5 Breen's remaining fraud-based claims are for Common Law Fraud (Count VI),
 6 Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), and Negligent
 7 Misrepresentation (Count IX). Defendants argue that her claims fail because Breen
 8 cannot establish a false statement of material fact upon which she relied and because
 9 there was no special relationship between Defendants and Breen to give rise to a duty to
 10 disclose. Dkt. 66 at 24–25.

11 Breen is correct that the WPLA's scope of preemption "except[s] fraud,
 12 intentionally caused harm or a claim or action brought under the consumer protection act,
 13 chapter 19.86 RCW." RCW 7.72.010(4); *see also Bylsma v. Burger King Corp.*, 176
 14 Wn.2d 555, 559 (2013) (collecting cases holding the same). However, the WPLA does
 15 preempt any claims based on "misrepresentation, concealment, or nondisclosure, whether
 16 negligent or innocent[.]" RCW 7.72.010(4). Therefore, summary judgment is granted as
 17 to Breen's Negligent Misrepresentation claim.

18 Washington has adopted the nine common law elements of fraud, and, at its core,
 19 a fraud claim requires a false representation of material fact. *See Stiley v. Block*, 130
 20 Wn.2d 486, 505 (1996) (listing the nine elements). Defendants assert that there is no
 21 evidence of a representation by Defendants that was communicated to Breen upon which
 22 she relied. Breen retorts that she has put forth evidence "that Defendants made several

1 statements and representations that were untrue, deceptive, and misleading, and which
2 Dr. Mitchell *may* have relied on prior to Mrs. Breen's implant procedure." Dkt. 69 at 18
3 (emphasis added). However, as discussed in regard to Breen's failure to warn claim, the
4 evidence establishes that Dr. Mitchell did not rely upon any statements made by
5 Defendants prior to Breen's 2010 implant surgery. Furthermore, Breen has not put forth
6 any evidence that Defendants made any misrepresentations of material fact to her
7 specifically or that she actually relied on any statement made by Defendants. Absent that
8 essential evidence, summary judgment is granted as to Breen's Common Law Fraud
9 claim.

10 Breen's final fraud claims are for Fraudulent Concealment (Count VII) and
11 Constructive Fraud (Count VIII). Both claims require a "special relationship" between
12 the parties that gives rise to a duty to disclose. *See Giraud v. Quincy Farm & Chem.*, 102
13 Wn. App. 443, 452 (2000) (fraudulent concealment); *Green v. McAllister*, 103 Wn. App.
14 452, 467–68 (2000), *superseded by statute on other grounds*, RCW 25.05.250(2), as
15 recognized in *McLelland v. Paxton*, 11 Wn. App. 2d 181, 221–22 (2019) (constructive
16 fraud). Whether a duty to disclose exists is a question of law. *Colonial Imps., Inc. v.*
17 *Carlton Nw., Inc.*, 121 Wn.2d 726, 731 (1993). Defendants argue that, as a matter of law,
18 no special relationship or duty to disclose exists between a medical device manufacturer
19 and a patient. Indeed, Washington law establishes that "a manufacturer has a duty to warn
20 the medical profession and not the user of its risks." *Terhune* 90 Wn.2d at 18. Breen does
21 not cite to or provide case law to the contrary. The Court therefore concludes, as a matter
22

1 of law, that Defendants did not owe a duty of disclosure to Breen. Summary judgment is
2 granted as to Breen's Fraudulent Concealment and Constructive Fraud claims.

3 **D. Punitive Damages & Discovery Rule and Tolling**

4 Finally, Defendants move for summary judgment on Breen's Punitive Damages
5 and Discovery Rule and Tolling claims, arguing that these are not recognized causes of
6 action in Washington. Defendants are correct that Washington law prohibits punitive
7 damages in a product liability action. *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d
8 1163, 1174 (W.D. Wash. 2006). They are also correct that the discovery rule is not its
9 own cause of action, but rather is a doctrine that determines when a cause of action
10 accrues. See *Green*, 136 Wn.2d at 95 (explaining the application of Washington's
11 discovery rule). Defendants' motion for summary judgment as to Breen's Punitive
12 Damages and Discovery Rule and Tolling claims is therefore granted.

13 **IV. ORDER**

14 Therefore, it is hereby **ORDERED** that Defendants' motion for summary
15 judgment, Dkts. 22, 66, is **GRANTED**.

16 The Clerk shall enter a **JUDGMENT** and close the case.

17 Dated this 22nd day of February, 2021.

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BENJAMIN H. SETTLE
United States District Judge
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